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Br J Cancer 1996 Jan;73(1):101-5

Phase II study of gemcitabine in patients with advanced pancreatic cancer.

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The efficacy and safety of gemcitabine at a starting dose of 800 mg m2 administered once a week for 3 weeks with 1 week's rest was investigated in chemonaive patients with advanced and/or metastatic pancreatic cancer. Of 34 patients, 32 were evaluable for efficacy, 20 patients had metastatic stage IV disease, 25 had a performance status of 1 and 26 (76%) patients has significant pain on presentation. All responses were independently validated by an external oncology review board: two patients achieved a partial response that lasted 5.8 and 5.2 months (6.3%) and six patients were stable for at least 4 weeks. The median duration of survival for evaluable patients was 6.3 months (range 1.6-19.2 months). The tumour markers, CEA, CA 19-9 and CA 195 were serially measured in 16 patients. There was a good correlation with tumour response when all three markers were significantly decreased. In 4 of 16 patients, tumour marker levels decreased by > or = 60%, including the two responders, one patient who survived for 12 months and one patient who showed objective tumour shrinkage but was deemed ineligible for response evaluation because the disease was considered not to be bidimensionally measurable. Symptomatic benefits included improvement in performance status (17.2%), analgesic requirement (7.4%), pain score (28.6%) and nausea (27.3%). The mean number of cycles administered was 2.5 and the mean dosage received was 890 mg m2 per injection. Seventy-four per cent of dose administrations were given on schedule. Toxicity, particularly haematological toxicity, reported as the maximum WHO grade experienced by patients was mild. Infective episodes were rare and limited to WHO grade 2 (6.7%). Nausea and vomiting was generally modest (WHO grade 3, 26.7%). Other side-effects included mild transient flu-like symptoms (seven patients) and peripheral oedema (three patients), which was not associated with abnormal cardiac hepatic or renal function. Gemcitabine has modest activity in pancreatic cancer, a limited positive improvement on a range of patient benefit parameters and has a mild toxicity profile. For these reasons and because of its novel mode of action, gemcitabine warrants further investigation in combination studies in pancreatic cancer.

Publication Types:

- Clinical trial
- Clinical trial, phase ii